IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NATERA INC., Plaintiff, v. ARCHERDX, INC., ARCHERDX, LLC, and INVITAE CORPORATION, Defendants.	C.A. No. 20-cv-125-GBW (Consolidated) **REDACTED PUBLIC VERSION**

MEMORANDUM ORDER

Plaintiff Natera Inc. ("Natera") sued Defendants ArcherDx, Inc., ArcherDx, LLC., and Invitae Corporation (collectively, "Invitae") for patent infringement. Upon conclusion of the jury trial, the jury returned a verdict finding that Defendants' products Personalized Cancer Monitoring ("PCM"), Stratafide, and LiquidPlex infringe U.S. Patent Nos. 10,557,172 (the "'172 patent") and U.S. Patent No. 10,731,220 (the "'220 patent"). D.I. 609. The jury also found that Defendants' products PCM, Stratafide, VariantPlex, and FusionPlex infringe U.S. Patent No. 10,597,708 (the "'708 patent"). *Id.* None of the asserted claims was found to be invalid by the jury, and the jury did not find that PCM was subject to the FDA safe harbor under 35 U.S.C. § 271(e)(1). *Id.* Thereafter, the Court held a one-day bench trial on prosecution laches, and ultimately found that Defendants failed to demonstrate that the patents were invalid for prosecution laches. D.I. 662. Natera now moves for an injunction against PCM. D.I. 621.

I. LEGAL STANDARD

Courts may "grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable." 35 U.S.C. § 283. A party seeking a permanent injunction must demonstrate (1) irreparable injury;

(2) inadequacy of remedies available at law, such as monetary damages; (3) the balance of the hardships between plaintiff and defendant warrants granting a remedy; (4) the public interest is not harmed by an injunction. *eBay Inc. v. Mercexchange, L.L.C.*, 547 U.S. 388, 393 (2006). The "movant must prove that it meets all four equitable factors." *Nichia Corp. v. Everlight Americas, Inc.*, 855 F.3d 1328, 1341 (Fed. Cir. 2017). In particular, "[i]f a plaintiff fails to show 'that the public interest would not be disserved by a permanent injunction,' then the district court may not issue an injunction." *Amgen, Inc. v. Sanofi*, 872 F.3d 1367, 1381 (Fed. Cir. 2017) (quoting *eBay*, 547 U.S. at 391).

II. DISCUSSION

Invitae has asserted that it is phasing out most of its use of the legacy PCM. D.I. 648 ¶ 11; D.I. 671. Invitae has indicated that will continue using the legacy PCM (1) in ongoing clinical trials and studies with AstraZeneca, Bristol Myers Squibb, and [redacted] (2) in ongoing research studies (TRAK-ER, ARTEMIS, and MARIA) with hospitals, academics, and pharmaceutical companies; (3) by potentially updating data on old studies if necessary as part of peer-review (4); to re-run limited additional tests for quality control for regulators or customers; and (5) for 50 patients. D.I. 648 ¶¶ 20-35; D.I. 622 at 20. Natera does not seek to enjoin the use of the legacy PCM for the patients but seeks an injunction on all other uses, including any uses Invitae has not yet indicated it will undertake. D.I. 622 at 20.

A. The Court Declines to Enjoin the Use of Legacy PCM in Ongoing Clinical Trials, for Updating Old Studies Undergoing Peer Review, and for Limited Quality Control, Because an Injunction Would Impermissibly Harm the Public Interest.

Invitae argues at length that enjoining its ongoing uses of legacy PCM would harm the public. The Court agrees that enjoining the use of legacy PCM in ongoing clinical trials and studies, for updating old studies, and for limited quality control would harm the public interest. Thus, the Court denies Natera's motion for an injunction as to those uses.

1. Ongoing Clinical Trials

Third-party companies are relying on the legacy PCM to conduct cancer research. Once a study design has been locked in, it is "very difficult to change that test, if not, nearly impossible." D.I. 647, Ex. A, Bench Trial Tr. 175:15–176:17 (Stefanelli). Changing the PCM would result in a confounding variable and may result in the stop of research in progress. *Id.* Natera argues that the changing the PCM is possible, since Invitae is using the PCM on stored samples. D.I. 657 at 8 (quoting D.I. 648 ¶ 20). However, Natera only cites evidence that the PCM is being used exclusively on stored samples for one of the three ongoing clinical studies, and the Court has no indication that all samples have been stored for all three clinical studies. *Id.* In any event, forcing third parties to re-run PCM for thousands of stored samples could significantly obstruct ongoing cancer research. *See* D.I. 647, Ex. A, Bench Trial Tr. 175:15-176:17 (Stefanelli). Impeding ongoing cancer research would significantly harm the public interest. *See Alcon, Inc. v. Teva Pharms. USA, Inc.*, Civ. No. 06–234–SLR, 2010 WL 3081327, at *3 (D. Del. Aug. 5, 2010) (denying a permanent injunction because an injunction would "deprive the public of the benefit of [a drug manufacturer's] developmental efforts."). Accordingly, the Court denies Natera's motion for an injunction on the use of legacy PCM in ongoing clinical trials and studies.

2. Updating Old Studies in Already Completed Research

Some researchers who have already used the legacy PCM may seek to publish their research. D.I. 648 ¶ 32. As part of peer-review, publishers may request the researchers to conduct additional PCM tests. *Id.* ¶ 33. Changing the PCM used for these new tests would introduce a confounding variable, and thus potentially prevent the publishing of the studies. *Id.* Natera does not specifically address this potential use. *See* D.I. 657 at 8-9. The Court accordingly finds that enjoining this use would significantly harm the public's interest in speedy and accurate research.

See Bio-Rad Lab'ys, Inc. v. 10X Genomics Inc., 967 F.3d 1353, 1379-80 (Fed. Cir. 2020) (affirming a carve-out from a permanent injunction for in-progress research). Thus, the Court denies Natera's motion for an injunction on the use of legacy PCM in already-completed research.

3. Limited Quality Control Uses

Regulators or customers may request that Invitae verify the accuracy of an already-performed test using the legacy PCM. D.I. 648 ¶ 34. Natera does not discuss or specifically object to these limited quality control uses. See D.I. 657 at 8-9. The public has an interest in ensuring that already-performed tests were accurate—if Invitae could not tell past patients if a test was accurate, patient care would be harmed. Meanwhile, Invitae has represented that these uses will be limited, dampening any public interest in enforcing an injunction against them. Ensuring an already performed test was accurate is not the sort of market activity that Natera would be able to capture. *Cf.* Section II.B.iv, *infra* (discussing sales Natera could capture). Any injunction must be reasonable and fit the principles of equity. 35 U.S.C. § 283. The Court finds the public interest in permitting accurate quality control weighs against an injunction. Thus, the Court denies Natera's motion for a permanent injunction on the use of legacy PCM to perform limited quality control on already-performed tests.

B. The Court Enjoins the Use of Legacy PCM in Research Studies and All Other Non-Exempted Uses.

Invitae has indicated that it intends to phase out the use of its legacy PCM in ongoing research studies (TRAK-ER, ARTEMIS, and MARIA). D.I. 648 ¶¶ 20-22, 31; D.I. 671. Invitae has represented that it has designed a non-legacy PCM that is able to substitute into research studies, and other uses in the future. D.I. 648 ¶¶ 11-16; D.I. 671. However, a promise to transition to a non-infringing alternative does not necessarily justify denying an injunction. *See Callaway Golf Co., v Acushnet Co.*, 585 F. Supp. 2d 600, 622 (D. Del. 2008), *rev'd on other grounds*, 576

F.3d 1331 (Fed. Cir. 2009) ("Defendant suggests allowing it to infringe until. . . it plans to launch a new version of the [infringing product]. The court is not in the business of making defendants' infringements easier to unravel."); *E.I. DuPont de Nemours and Co. v. Unifrax I LLC*, No. 14-1250-RGA, 2017 WL 4004419, at *4-6 (D. Del. Sept. 12, 2017) ("[A] bare promise by a party in the course of litigation to discontinue past or ongoing misconduct does not justify denial of injunctive relief."). Thus, the Court applies the full *eBay* equitable analysis. In applying the equitable factors, the Court finds that all four factors favor granting an injunction in Natera's favor.

i. Irreparable Injury

First, Natera would suffer irreparable injury if the legacy PCM is not enjoined. The PCM market is nascent, and there are significant first-mover advantages. D.I. 648 ¶¶ 111, 114. Invitae has represented that it is possible to substitute an alternative PCM into the ongoing research studies and has not provided a reason that this substitution cannot be with Natera's competitive product rather than Invitae's new PCM. *See* D.I. 648 ¶¶ 11-16; D.I. 646 at 6-8. That Natera and Invitae are competitors and Natera has lost market share strongly suggests irreparable harm. *Broadcom Corp. v. Emulex Corp.*, 732 F.3d 1325, 1338 (Fed. Cir. 2013). This is especially true where Natera has not licensed competitors to sell tests. *Presidio Components, Inc. v. Am. Tech. Ceramics Corp.*, 702 F. 3d 1351, 1363-64 (Fed. Cir. 2012); D.I. 622, Ex. 4, Trial Tr. 630:11-14. Invitae's infringing competitive product threatens to erode prices, by increasing the number of competitors and limiting the ability of Natera to charge a profit-maximizing monopoly price. D.I. 627 ¶¶ 14-15. That there are other competitors in the broader cancer-testing market "does not negate irreparable harm," especially since the specific market (personalized cancer monitoring) was a two-company market until recently. *Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1151 (Fed. Cir. 2011); D.I. 629. The new non-infringing PCM also does not alter this analysis. There is no

evidence in the record that the new non-infringing PCM is a perfect substitute for Natera's product. *See generally* D.I. 648. Therefore, there is still a significant risk of price erosion and loss of market share from the legacy PCM, if its use were not enjoined.

Natera also would continue to suffer reputational harm. Natera suffered reputational harm and lost customer goodwill from losing the TracerX study and other projects to Defendants' legacy PCM. D.I. 622, Ex. 3, Trial Tr. 592:3-9 (losing TracerX study "was quite public" and after being published on the cover of Nature "when people found out cancer research in UK and professor [Swanton] were going with different technology everybody started asking questions why that happened is there something wrong with Natera."); D.I. 623 Ex. 1 ("Malani Rpt.") ¶¶ 175-176. Invitae argues that Natera's loss of goodwill was compensated by the jury, but "a finding of lost profits demonstrates that a plaintiff was deprived of market share and business opportunities *in addition* to lost profits." *freal Foods, LLC v. Hamilton Beach Brands, Inc.*, No. CV 16-41-CFC, 2020 WL 4015481, at *4 (D. Del. July 16, 2020) (emphasis added). Invitae also argues that Natera caused its own harm, since Dr. Swanton was unhappy with them. D.I. 646 at 11. However, Invitae's infringing alternative product was a necessary condition for Dr. Swanton's unhappiness to be manifested in a public product switch. Natera suffered irreparable reputational damage from Invitae's infringement.

Invitae advances three more arguments that Natera has not suffered irreparable harm: (1) that Natera waited too long to file its claims; (2) that Natera is not using the patented technology itself; and (3) that Natera's patented technology does not drive purchasing decisions because Invitae was able to create a non-infringing alternative with comparable accuracy. D.I. 646 at 8-14. Each of these arguments fails.

First, delay in filing, or in seeking a preliminary injunction, need not be considered when evaluating whether to grant a permanent injunction. *800 Adept, Inc. v. Murex Securities, Ltd.*, 505 F. Supp. 2d 1327, 1335-37 (M.D. Fla. 2007) (holding that even a delay significant enough to prevent pre-judgment interest does not weigh against an irreparable injury); *see Mytee Prod., Inc. v. Harris Rsch., Inc.*, 439 F. App'x 882, 888 (Fed. Cir. 2011) ("While we have held that delay in seeking an injunction is a factor to be considered in determining whether to issue a preliminary injunction, we have never held that failure to seek a preliminary injunction [and its consequent delay] must be considered as a factor weighing against a court's issuance of a permanent injunction.").

Second, that Natera does not practice the invention does not disprove irreparable injury. "Although a patentee's failure to practice an invention does not necessarily defeat the patentee's claim of irreparable harm, the lack of commercial activity by the patentee is a significant factor in the calculus." *High Tech Med. Instrumentation, Inc. v. New Image Indus., Inc.*, 49 F.3d 1551, 1556 (Fed. Cir. 1995). Here, the patentee does have commercial activity, and the two companies are direct competitors. *See* D.I. 622, Ex. 2, Trial Tr. 240:10-12. This case is thus unlike the genre of cases dealing with non-practicing entities, since there is a clear record of commercial and irreparable harm to Natera's business model. *See Presidio*, 702 F.3d at 1363 ("Even without practicing the claimed invention, the patentee can suffer irreparable injury.").

Third, Invitae's allegations that it was able to design a non-infringing design-around do not weigh against a finding of irreparable harm. Invitae argues that, because it was able to design-around the patented technology with accurate tests, Natera failed to show a "nexus" between the technology and purchasing decisions. D.I. 646 at 13-14. However, the Court has not analyzed whether Invitae's new technology is non-infringing, nor if it is equally accurate. Also, all Natera

needs to do is show that there is "some connection between the harm alleged and the infringing acts." *Apple Inc. v. Samsung Electronics*, 809 F.3d 633, 640 (Fed. Cir. 2015). Natera has demonstrated that its patented technology aided accuracy of tests, and Invitae's own expert conceded that the implementation of the patented technology was "extremely valuable" in PCM. *ArcherDX v. Qiagen LLC*, No. 18-1019-MN, D.I. 537, Ex. 66, at 4 (D. Del.).

"Price erosion, loss of goodwill, damage to reputation, and loss of business opportunities are all valid grounds for finding irreparable harm." *Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 930 (Fed. Cir. 2012). Thus, the Court finds that Natera is suffering irreparable harm, which favors an injunction.

ii. Inadequacy of Remedies Available at Law

The second factor, inadequacy of remedies available at law, is nearly indistinguishable from irreparable injury. *Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1155 (Fed. Cir. 2011) ("With respect to the adequacy of money damages, Bosch argues that it will continue to suffer irreparable harm . . . ."); *Apple*, 809 F.3d at 644-45 (holding that error on irreparable harm leads necessarily to error on inadequacy of remedies). Invitae's only new argument on inadequacy of remedies is that a "sunset royalty" would appropriately compensate Natera. *See* D.I. 646 at 18. However, sunset royalties are "inadequate to compensate Plaintiff . . . forced to compete against a rival gaining market share with Plaintiff's technology." *E.I. DuPont de Nemours & Co. v. Unifrax I LLC*, No. CV 14-1250-RGA, 2017 WL 4004419, at *4-6 (D. Del. Sept. 12, 2017). A sunset royalty would maintain first-mover advantage and aggravates the risk of price erosion discussed above. *See id*; Malani Rpt. ¶¶ 122-25. The Court has already found "loss of market share, brand recognition, and customer goodwill," factors which demonstrate inadequacy of monetary damages, "particularly when the infringing acts significantly change the relevant market." *i4i Ltd.*

P'ship v. Microsoft, Corp., 598 F.3d 831, 862 (Fed. Cir. 2010). Accordingly, the Court finds that the remedies available at law are unable to adequately compensate Natera.

iii. Balance of Hardships

The balance of hardships favors granting an injunction. All of Invitae's arguments on the balance of hardships relate to the clinical trials and studies, which the Court has already decided not to enjoin. D.I. 646 at 14-16. Invitae began the research studies after the filing of the lawsuit in January 2020. See D.I. 658 Ex. 72, Ex. 73, Ex. 74. Similarly, any other enjoined use would be initiated after the trial began. When the harms an infringer faces are "almost entirely preventable" and triggered by a "calculated risk to launch its product pre-judgment," the balance of hardships strongly tilts in favor of the patentee. *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1383 (Fed. Cir. 2006); *see also Windsurfing Intern'l, Inc. v. AMF, Inc.*, 782 F.2d 995, 1003 n. 12 (Fed. Cir. 1986) (One "who elects to build a business on a product found to infringe cannot be heard to complain if an injunction against continuing infringement destroys the business so elected."). Thus, this factor favors granting an injunction.

Moreover, revenues from PCM are a small fraction of Invitae's total business. D.I. 627 ¶ 11, D.I. 624, Ex. 22, 12. In contrast, it is the primary driver of long-term growth for Natera. D.I. 624, Ex. 23, 1. Comparing the "parties' sizes, products, and revenue sources," the Court finds that these traditional factors also indicate that the balance of hardships tilts in favor of granting an injunction. *i4i Ltd. P'ship,* 598 F.3d at 862-63 (when the infringing product "relates to only a small fraction" of a defendant's revenue, the balance of hardships tilts towards plaintiff.).

Further, the representation from Invitae that it is phasing out the use of the legacy PCM weighs in favor of an injunction on any future not yet contemplated uses, as well as on the research

studies. D.I. 648 ¶ 11; D.I. 671. Invitae has itself indicated that it has an option other than continuing to infringe, so any hardship it suffers is limited. D.I. 671.

iv. Public Interest

For the non-excepted uses, the public interest weighs in favor of an injunction. Invitae argues that the public interest for the research studies favors an injunction because "[i]f the Court orders Invitae to immediately stop using the legacy PCM—before Invitae is able to transition the studies to the updated PCM—the Court would necessarily also halt the TRAK-ER study and the other ongoing trials and studies." D.I. 646 at 17. However, Invitae has not provided any reason why the updated PCM can replace the legacy PCM in the studies, but Natera's competitive product cannot. *See* D.I. 646 at 16-18. Naterae's competitive product, Signatera, appears to be equally accurate, covers all the same diseases, and has sufficient capacity to meet the market's needs. *See* D.I. 623, Ex. 4, Trial tr. 624:18-20 (equally accurate); D.I. 624, Ex. 24, 25, 26, 27 (same diseases), D.I. 622 at 18 (capacity). In circumstances where "the public can obtain the products from [Plaintiff]" the public interest does not disfavor an injunction. *Celsis*, 922 F.3d at 932. Instead, given the "importance of the patent system in encouraging innovation" and "the encouragement of investment-based risk," the public interest for the remaining uses favors an injunction. *Apple*, 809 F.3d at 647; *Sanofi-Synthelabo*, 470 F.3d at 1383. Thus, the Court finds that the public interest factor favors an injunction on the research studies, and on any use not specifically exempted.

Because all four factors support granting an injunction for the remaining uses, the Court GRANTS-IN-PART Natera's motion for a permanent injunction.

Therefore, at Wilmington this 21st day of November 2023, **IT IS HEREBY ORDERED** that Plaintiff Natera Inc.'s ("Natera") Motion for Permanent Injunction (D.I. 621) against Defendants ArcherDx, Inc., ArcherDx, LLC., and Invitae Corporation (collectively, "Invitae"), is **GRANTED-IN-PART.**

Defendants and each of their officers, servants, employees, attorneys, and any other persons who are in active concert or participation with them, are hereby permanently enjoined from infringing in any ways Claims 1, 6, and 8 of U.S. Patent No. 10,557,172; claims 1, 3, 4, 6, and 7 of U.S. Patent No. 10,731,220; and claims 1 and 19 of U.S. Patent No. 10,597,708, by using PCM or any product or service not more than colorably different from PCM, through and including the respective expiration date of each patent, including any USPTO extensions granted thereon, with the following exceptions:

A. Using PCM in currently ongoing clinical trials and studies with AstraZeneca, Bristol Myers Squibb, and [redacted]

B. Using PCM to update data in old studies if necessary as part of peer-review;

C. Using PCM to re-run limited additional tests for quality control for regulators or customers;

D. Using PCM for the few patients using PCM as of the effective date of this injunction.

Defendants shall file with the Court under seal and serve on all parties a notice identifying all additional uses of PCM performed under this injunction. Plaintiff shall have the right to challenge these identifications. The Court retains jurisdiction to enforce the judgment and permanent injunction pertaining to this action.

GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE